

REMARKS/ARGUMENTS

Upon entry of the present amendment, claims 384, 386, 387, 392, 394-396 and 402 are pending in the application. Claims 384, 386, 392 and 394 are amended, claims 370-383, 385, 388-391, 393 and 397-401 are canceled, and new claim 402 is added by the present amendment.

Support for the amendments to claim 384 can be found in the specification at, e.g., paragraphs 0008, 0013 and 0015 of the published international application (WO 2005/058940). Support for new claim 402 can be found in the specification at, e.g., paragraph 0130 of the published international application. Claims 386, 392 and 394 are amended to modify the claim dependency. No new matter is added.

Claim Objections

Claims 384-391 are objected to because the subscripted “P” in the recited formula should be a lower case “p”.

Independent claim 384 has been amended as suggested. All other pending claims depend directly or indirectly from claim 384. Accordingly, Applicants respectfully request withdrawal of this ground of objection.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

Claims 388-396 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the claims depend from withdrawn claim 377.

Claim 392 has been amended to depend from claim 384. Each of the other rejected claims still pending in the application depends directly from claim 392. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

Claim Rejections - 35 U.S.C. § 102

Conley et al.

Claims 384, 385, 387-389, 391-393 and 395 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Conley *et al.* (WO 01/93804; published 2001). This reference is

identified in the Office Action as publication number “WO 02/93804”, rather than WO 01/93804. Applicants believe this is a simple typographical error, but request clarification if otherwise (Publication No. WO 02/93804 is entitled “Method and System for Provisional Digital Subscriber Line Facilities” and the first named inventor is Klos).

Without agreeing with the Examiner, Applicants have amended independent claim 384 to recite a carrier protein selected from the group consisting of CRM₁₉₇, *Streptococcus pyogenes* ORF1224, *Streptococcus pyogenes* ORF1664, *Streptococcus pyogenes* ORF2452, *Chlamydia pneumoniae* ORF T367, and *Chlamydia pneumoniae* ORF T858.

Conley discusses the conjugation of a carrier protein to one or more hepatitis C virus mimotopes. *See abstract.* Each of the exemplified conjugates discussed in Conley comprises an OMPC (Outer Membrane Protein Complex of *Neisseria meningitidis*) carrier attached to one or more of the mimotopes. Conley does not discuss conjugates comprising any one of the recited carrier proteins.

It is well established that for a prior art reference to anticipate a claimed invention, the prior art reference must teach each and every element of the claimed invention. *See* MPEP §2131. Applicants submit that Conley does not teach each and every element of the claimed invention, as recited in independent claim 384. In particular, Conley does not teach a conjugate comprising any one of the carrier proteins recited in claim 384. Thus, claim 384 is not anticipated by Conley for at least the reasons discussed above. All other pending claims depend directly or indirectly from claim 384 and are patentable over Conley for at least the reasons discussed above. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

Mariotti et al.

Claims 392-395 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Mariotti *et al.* (Vaccine 20:2229-2239 (2002)).

Mariotti discusses the immunogenicity of an anti-*Haemophilus influenzae* type b CRM₁₉₇ conjugate. *See abstract.* Mariotti does not discuss capping the CRM₁₉₇ in any capacity.

As discussed above, claim 392 has been amended to depend from independent claim 384, which is not the subject of a rejection under 35 U.S.C. 102(b) on the basis of Mariotti. Further, Applicants submit that Mariotti does not discuss a conjugate comprising a capping molecule, as recited in independent claim 384. For at least this reason, Mariotti does not teach each and every element of the presently claimed invention. Thus, Mariotti does not anticipate the presently claimed invention. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

Claim Rejections - 35 U.S.C. § 103

Conley et al.

Claims 392 and 396 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Conley *et al.*, *supra*.

As discussed above, claim 392 has been amended to depend from independent claim 384. Claim 384 is directed to a conjugate comprising a peptide immunogen attached to one of a specified group of carrier proteins, and comprising a capping molecule attached to a derivatized functional group of the carrier protein, while preserving the functionality of the carrier such that it retains its ability to elicit the desired immune response against the peptide immunogen that would otherwise not occur without a carrier. As demonstrated in Examples 1, 6 and 9 of the specification, preservation of the “carrier effect” has been confirmed in connection with each of the recited capped carrier proteins.

Conley does not discuss conjugates comprising any one of the carrier proteins recited in claim 384. Thus, at least this element of the claimed invention is absent from Conley, and no rationale has been provided to explain why a skilled person would have found it obvious to substitute the carrier proteins recited in claim 384 for the OMPC carrier of Conley to arrive at the presently claimed invention. In particular, use of chemical capping reagents to inactivate the unreacted derivatized functional groups on the carrier protein may be disruptive to the functionality of the immunogenic conjugates. *See* the discussion in the specification at paragraph 0008 (WO 2005/058940). Thus, the single example provided in Conley would not have provided the skilled artisan with a reasonable expectation that the carrier proteins recited in

claim 384 could be capped while preserving the functionality of the carrier such that it retains its ability to elicit the desired immune response against the peptide immunogen that would otherwise not occur without a carrier, as claimed.

In view of the foregoing, Applicants submit that the presently claimed invention is patentable over Conley. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

Conley et al. in view of Mariotti et al.

Claims 384-386, 388-390 and 392-394 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Conley *et al.*, *supra* in view of Mariotti *et al.*, *supra*.

As discussed above, Conley does not discuss conjugates comprising any one of the carrier proteins recited in claim 384. Mariotti discusses a conjugate comprising a CRM₁₉₇ carrier protein. However, Mariotti makes no mention of capping in connection with the CRM₁₉₇ carrier protein, as claimed. Thus, between the two references only a single example of a conjugate comprising a capped carrier protein (OMPC) is provided. As mentioned above, the use of chemical capping reagents to inactivate the unreacted derivatized functional groups on the carrier protein may be disruptive to the functionality of the immunogenic conjugates. Thus, the single example directed to a capped OMPC carrier would not have provided the skilled artisan with a reasonable expectation that the carrier proteins recited in claim 384 could be capped while preserving the functionality of the carrier such that it retains its ability to elicit the desired immune response against the peptide immunogen that would otherwise not occur without a carrier, as claimed.

In view of the foregoing, Applicants submit that the presently claimed invention is patentable over Conley in view of Mariotti. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

Mariotti et al. in view of Conley et al.

Claims 384-391 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Mariotti *et al.*, *supra* in view of Conley *et al.*, *supra*.

As discussed above, Mariotti discusses a conjugate comprising a CRM₁₉₇ carrier protein, but does not discuss capping in connection with the carrier protein in any capacity. Conley discusses and exemplifies a capped conjugate comprising an OMPC carrier protein. Neither reference teaches or otherwise suggests that the carrier proteins recited in claim 384 could be capped while preserving the functionality of the carrier such that it retains its ability to elicit the desired immune response against the peptide immunogen that would otherwise not occur without a carrier, as claimed.

In view of the foregoing, Applicants submit that the presently claimed invention is patentable over Mariotti in view of Conley. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.


Double Patenting

Claims 384-396 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 398 of copending Application No. 10/583,503.

Without agreeing with the Examiner's position, Applicants will consider submitting a terminal disclaimer in compliance with 37 C.F.R. 1.321, if appropriate, upon resolution of other rejections of the claims.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,


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